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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,332	09/08/2006	Graeme Semple	22578-004US1 059.US2.PCT	9629
26204 7590 12/05/2008 FISH & RICHARDSON P.C. P.O. BOX 1022 MINNEAPOLIS, MN 55440-1022			EXAMINER CHU, YONG LIANG	
			ART UNIT	PAPER NUMBER
			1626	
			NOTIFICATION DATE	DELIVERY MODE
			12/05/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

Office Action Summary	Application No. 10/560,332	Applicant(s) SEMPLE ET AL.	
	Examiner YONG CHU	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 August 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,152-170 and 172-187 is/are pending in the application.
- 4a) Of the above claim(s) 165 and 179-187 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,152-164,166-170 and 172-178 is/are rejected.
- 7) ☒ Claim(s) 1, 152-164, 166-170, and 172-178 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 December 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>08/28/2008</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1, 152-170, and 172-187 are pending in this application. Claims 165 and 179-187 are non-elected subject matter.

Information Disclosure Statement

Applicants' Information Disclosure Statement, filed 08/28/2008 has been considered. Please refer to Applicant's copy of the PTO-1449 submitted herewith.

Response to Amendment

The Amendment by Applicants' representative Dr. Susanne H. Goodson dated on 08/28/2008 has been entered.

Response to Arguments

Argument over the rejection of claims under 35 U.S.C. §112, 1st paragraph

Applicants' arguments over the rejection of claims 1, 152-164, 166-170 and 172-176 for the scope of compounds failing to meet the enablement requirement *under 35 U.S.C. §112, 1st paragraph* have been considered, and are found persuasive. Therefore, the rejection has been withdrawn.

Applicants' arguments over the rejection of the **solvates** and **hydrates** in claims 1, 152-164, 166-170 and 172-178 for failing to meet the enablement requirement *under 35 U.S.C. §112, 1st paragraph* have been considered, but found not persuasive. As stated in the previous Office action, a hydrate or a solvate is a form of crystal wherein a

Art Unit: 1626

specific number of water or organic solvent molecule binds to an organic compound to form a crystal 3-D lattice structure. Not all organic compounds can form hydrates or solvates, and formation of hydrate or solvate is unpredictable. Even though there is a general recrystallization procedure, the procedure can not be applied to any organic compounds for making solvate or hydrate. Even for the organic compounds can form solvates or hydrates, the process for making such solvates or hydrates are very unpredictable even with a reference in hand. Recrystallization process varies on the specific compounds; it requires a try under various recrystallization conditions for each individual solvates or hydrates involving various factors such as solvents, temperature, crystal seed, speed of heating the solvents and solvent concentration etc. It is well known a polymorphism can be patentably distinct from a regular non-crystal compound even they are the same substance. Therefore, the rejection is maintained.

Because the instant specification fails to describe the specific very unpredictable solvates or hydrates of the instantly claimed compounds, the instant specification does not describe stoichiometry of the individual solvate or hydrate, a specific method for making each individual solvate or hydrate, and any x-ray diffraction data to prove the identity of the claimed solvates or hydrates. Therefore, the rejection for failing to comply with the written description requirement is maintained.

Argument over ODP rejection

Applicants' arguments have been considered, but found not persuasive. The specification does not demonstrate the criticality as an alkoxy chain distinct from alkyl

Art Unit: 1626

chain toward the claimed utility. Furthermore, the '902 application teaches many possible chains in R^3 such as alkyl substituted with alkoxy, which is obvious to one skilled in the art to predict an interchange alkyl with alkoxy without changing the utility of the claimed compounds, and therefore the instantly claimed compounds having alkoxy is obvious over the '902 compound having alkyl group. In addition, as being recognized by Applicants, if **X** as $-O-$, and $-S-$ are enabled, then **X** as $-S(O)-$ and $-S(O)_2-$ are also considered enabled without further support from working examples. The alkoxy and alkyl is obvious variation in view the teachings of the '902 application as whole. Therefore, the rejection is maintained.

Claim objection

The provisionally objected claims still contain non-elected subject matter. The current elected subject matter is rejected under 112(i) and ODP. Extended search and examination is not required, because of the pending rejections and lacking unity of invention, see MPEP§803.02. Therefore, the objection is maintained.

Conclusion

- No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

Art Unit: 1626

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Chu whose telephone number is 571-272-5759. The examiner can normally be reached on 7:00 am - 3:30 pm EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph M^oKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Status Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Application/Control Number: 10/560,332
Art Unit: 1626

Page 6

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